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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,321	12/04/2001	Stefan Brust	38137-0019	1464

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/000,321	BRUST ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-49* is/are pending in the application.

4a) Of the above claim(s) *36-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply ...*.

Detailed Office Action

37 C.F.R. § 1.126

Applicants are reminded that the numbering of claims is not in accordance with 37 C.F.R. § 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 C.F.R. § 1.121(b), they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). This application contained originally filed claims 1-23. The preliminary amendment submitted 04 December, 2001, canceled claims 1-27 without prejudice or disclaimer and introduced new claims 30-55. Accordingly, originally presented claims 1-23 have been canceled without prejudice or disclaimer and **misnumbered claims 30-55 have been renumbered 24-49, respectively. Applicants should employ the correct claim numbering in all future amendments**

Status of the Claims

Applicants' election with traverse of Group I (claims 24-35) in the communication received 10 November, 2003, is acknowledged. The traversal is based upon the premise that it would not be unduly burdensome for the Examiner to search and examine all groups simultaneously. This is not found persuasive for the reasons of record clearly set forth in the last Office action. As previously set forth, restriction to one of the following inventions was required under 35 U.S.C. § 121:

a. Group I, claim(s) 24-35, drawn to **human immunodeficiency virus type 1 (HIV-1) peptides**, classified in class 530, subclasses 300 and 324-326.

b. Group II, claim(s) 36-41, drawn to **methods and diagnostic kits for the detection of retroviral antibodies** employing a viral peptide, classified in class 435, subclass 7.1.

c. Group III, claim(s) 42 and 43, drawn to a **method for immunizing against retroviral infection** through the administration of a suitable composition, classified in class 424, subclasses 188.1 and 208.1.

d. Group IV, claim(s) 44, drawn to a **nucleic acid** encoding an HIV-1 peptide, classified in class 536, subclass 23.72.

e. Group V, claim(s) 45-49, drawn to **methods for the detection of HIV nucleic acids**, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the identified groups are directed toward structurally and functionally disparate chemical molecules (e.g., amino acids or nucleic acids) with different attendant physical and chemical properties. Accordingly, each group is clearly directed toward a different inventive entity.

Inventions II/III/V are all are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified methodologies is directed toward a different scientific objective (e.g., immunization, antibody detection, nucleic acid detection) that employs different reagents (e.g., peptides, vaccinating compositions, nucleotide sequence primers) and protocols. Accordingly, each of the identified groups is clearly directed toward a different inventive concept.

Inventions I and II/III are related as product and processes of use. The inventions can be shown to be distinct if either or both

of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the peptides of Group I can be employed in a number of materially different processes such as antibody binding assays, receptor-ligand binding assays, antibody production, and viral inhibitory assays.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the peptides of Group I are neither required nor utilized by the methodology of Group V. Accordingly, each group is clearly directed toward a different invention.

Inventions IV and II/III/V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the nucleic acids of Group IV are neither required nor utilized by the methodologies of Groups II, III, and V. Accordingly, each group is clearly directed toward a novel inventive concept. Therefore, **the requirement is still deemed to be proper and is therefore made FINAL.** Claims 36-49 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention

35 U.S.C. § 120

If applicant desires priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of non-provisional application(s) (whether patented or

abandoned) should also be included. **If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application.** If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. If applicant desires priority based upon a National Stage filing, this information should also be referenced in the first sentence of the specification (i.e., This application is a National Stage entry of International Application No. PCT/CCPY/NNNNN, filed , 199N). Applicants are advised that the status of both U.S. Serial Nos. 09/131,551 and 08/394,021 have changed. The first paragraph of the specification should be amended to reflect these changes.

37 C.F.R. § 1.821-1.825

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The claims and figure 3 reference numerous amino acid and nucleotide sequences without providing the appropriate sequence identifiers.** Applicants are reminded that sequences appearing in the **specification** and/or **drawings** must also be identified by a sequence identifier (SEQ ID NO.:) in accordance with 37 C.F.R. § 1.821(d). Sequence identifiers for sequences appearing in the drawings may appear in the Brief Description of the Drawings. Applicants must provide appropriate amendments to the specification and/or drawings inserting the required sequence identifiers. Extensive amendments may necessitate the submission of a substitute specification.

37 C.F.R. § 1.97-1.98

The information disclosure statement filed 04 December, 2001, has been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 112, Second Paragraph

Claims 24-35 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims reference an "immunologically active" peptide which is vague and ambiguous since the precise properties referenced are not readily manifest. Perusal of the disclosure appears to suggest that the claimed invention should be directed toward "immunogenic" peptides. Appropriate correction is required.

Claim 26 also references antibodies that are specific to retroviruses of the "HIV type" which is also vague and ambiguous. The term HIV encompasses both HIV-1 and -2 and within these designations are various clades, sub-clades, and isolates. Moreover, these viruses display considerable genotypic/phenotypic heterogeneity when compared to one another. Thus, the precise binding specificity of the antibody of interest is not readily mainifest. For instance, is the antibody specific for HIV-1 gp41, HIV-2 gp36, or both TMPs? Appropriate correction is required.

Claim 33 references the amino acid sequence "NQQ ... KNW" which is confusing since it does not match any of the listed sequences. Perusal of the disclosure provides support for a peptide comprising the amino acid sequence "NQQ ... KWN". Appropriate correction is required.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in —

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 24-27 and 29-34 are rejected under 35 U.S.C. § 102(e) as being anticipated by Guertler *et al.* (1998a). Guertler and colleagues disclose HIV-1 peptides obtained from isolate MVP-5180/91 that meet all of the claimed limitations.

Claims 24-27 and 29-34 are rejected under 35 U.S.C. § 102(e) as being anticipated by Guertler *et al.* (1998b). Guertler and colleagues disclose HIV-1 peptides obtained from isolate MVP-5180/91 that meet all of the claimed limitations.

Statutory Type Double Patenting, 35 U.S.C. § 101

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. § 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an

invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S.P.Q. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 U.S.P.Q. 330 (C.C.P.A. 1957); and *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970). A statutory type (35 U.S.C. § 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer **cannot** overcome a double patenting rejection based upon 35 U.S.C. § 101.

Claims 24-35 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-12 of published application US2002123039A1. This is a **provisional** double patenting rejection since the conflicting claims have not in fact been patented.

Claims 24-35 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-12 of published application US2001009667A1. This is a **provisional** double patenting rejection since the conflicting claims have not in fact been patented.

Non-statutory Double Patenting

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969); *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970); *In re Van Ornum*, 686 F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); and *In re Goodman*, 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993). A timely filed terminal disclaimer in compliance with 37 C.F.R. ' 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-

statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. ' 1.78(d). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. ' 3.73(b).

Claims 24-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,830,634. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '634 patent are directed toward individual peptidic species that fall within the scope of the claims of the instant application.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

06 March, 2004